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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 7, 1997

Our Reference: 2953422

Avona L'Carttier, President
Arise & Shine
401 Berry Street
Mt. Shasta, CA 96067

WARNING LETTER

Dear Ms. L'Carttier:

The Food and Drug Administration (FDA) received a complaint regarding injuries sustained by a young woman who experienced an abnormal heart rate with complete heart block, a potentially life-threatening condition. The consumer's symptoms were consistent with an overdose of digitalis-like cardiac glycosides. The young woman experienced this condition after ingesting a regimen of dietary supplements. FDA's investigation determined that the problem was due to the ingredient plantain found in your dietary supplement "Chomper."

The Chomper products that you distributed are adulterated and misbranded under the Federal Food, Drug and Cosmetic Act (the Act) as follows:

- within the meaning of Section 402(a)(1) in that they contain an added poisonous or deleterious substance, namely lanatosides (cardiac glycosides), which may render them injurious to health.

- within the meaning of section 402(f)(1)(A) of the Act in that they are dietary supplements, which contain lanatosides, e.g. cardiac glycosides, which present a significant or unreasonable risk of illness under conditions of use recommended or suggested in the product's labeling.

- within the meaning of section 403(a)(1) in that the labeling is false and misleading because it fails to reveal the material fact that the products contain lanatosides, e.g. cardiac glycosides, which, if ingested, can cause life-threatening heart reactions.

The problem was associated with powdered plantain that you purchased from [redacted] and provided to your contract manufacturers for use in the manufacture of multiple lots of Chomper tablets, Chomper bulk powder, and Chomper with Cayenne capsules.

FDA collected a sample of Chomper (lot 703118) from the consumer discussed above and multiple samples (97-757-261/262, 97-732-784, 97-453-570/571, and 97-735-910/912) of powdered or cut plantain. These samples of plantain were collected from two of your contract manufacturers, from your supplier's custom miller, and from "reserves" of your supplier. FDA analyses of these samples showed that Chomper ([redacted]) and the plant material identified as "plantain" contained lanatosides (cardiac glycosides). The presence of lanatosides support that the plant material contains *Digitalis* glycosides. *Digitalis lanata* has been reported to contain these lanatosides, whereas, plantain has not been reported to contain any cardiac glycosides.

FDA also conducted an analysis of a sample of plantain to determine whether the material identified as plantain actually contained plantain. The analysis found that the characteristic trichomes for plantain were low in concentration in the sample when compared to reference specimens. These analyses indicate that the plantain was contaminated with *Digitalis*.

FDA also analyzed the sample of Chomper ([redacted]) which you sent to us. The analysis of this sample also showed the presence of lanatosides in the finished product. We are concerned that you did not alert FDA when you initially recalled Chomper ([redacted]) in 1996. You continued to manufacture this product through another contract manufacturer without adequately investigating the cause of the problem, now known to be caused by the contaminated plantain.

As an own label distributor, you are responsible for ensuring that ingredients you provide for the manufacture of your products and dietary supplements that you distribute are safe for human consumption. We note that you have voluntarily recalled the adulterated and misbranded Chomper products. However, we are concerned that this type of situation does not occur again. This matter obviously requires that you take steps to ensure that ingredients you provide for use in your dietary supplements are not contaminated.

We request that you notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to preclude these violations from occurring in the future. If you continue to distribute dietary supplements and foods that are adulterated and misbranded as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Your reply should be addressed to:

Sam M. Ali
Recall and Emergency Coordinator
U.S. Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502

Telephone (510) 337-6869
FAX (510) 337-6705

Sincerely,

Charlie D. Moss
Acting District Director
San Francisco District